510(k) Summary

JUN 2 8 2013

1. Submitter Information

Company name: Biotest Medical Corporation
Contact person: Fred Lee
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2. Name of Device

Trade Name: SOLUSmobile Blood Glucose Management System
(Model 6134)
Common Name: In Vitro Diagnostic Glucose Test System
Classification: Glucose Test System
21 CFR 862.1345 (Class II)
21 CFR 862.1660 (Class I)
Classification Panel: Clinical Chemistry
Product Code: NBW, System, Test, Blood Glucose, Over-the-Counter & Prescription.
CGA, Glucose Oxidase, Glucose
JJX, Quality Control Material

3. Predicate Device

Trade Name: SOLO V2 Blood Glucose Management System
(Model 6131)
Common Name: In Vitro Diagnostic Glucose Test System
Submitter: Biotest Medical Corporation
510(k) Number: K093764

4. Device Description

The SOLUSmobile (Model 6134) is a product kit consisting of blood glucose

meter, test strips, control solutions, a lancing device, lancets, battery charger and charging cable, and instructions for use.
To perform a test, a glucose test strip is inserted into the top of the monitor. When a small drop of blood is applied to the end of the test strip, glucose reacts with the reagents on the test strip, producing an electrical current that is proportional to the blood glucose concentration. The glucose concentration is calculated by the glucose meter and is based on the electrical current measured. The quantitative glucose concentration (in mg/dL or mmol/L) is displayed on the display screen.

An embedded cellular communications module within the SOLUSmobile meter enables automatic wireless data transmission over the Wireless cellular network between the meter and a Central Data Repository (Cloud server).

The test strips, control solutions, lancing device, and lancets are identical to previously cleared devices. The fundamental scientific technology of the SOLUSmobile except the device's communications capabilities remains unchanged from the legally marketed predicate device, SOLO V2 (K093764).

5. Intended Use/Indications for Use

• Intended Use:

See Indications for Use below.

• Indications for Use:

SOLUSmobile Blood Glucose Management System (Model 6134)

The SOLUSmobile Blood Glucose Management System is intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger and the forearm. It is intended for use by a single patient with diabetes mellitus at home as an aid in monitoring the effectiveness of a diabetes control program, and should not be shared. SOLUSmobile is not intended for the diagnosis of or screening for diabetes mellitus, nor for use in neonates. The alternative site testing (forearm) in this system can only be used during steady-state blood glucose conditions. This system contains an audible readout function that provides an audible message of test results for users. The SOLUSmobile Blood Glucose Management System uses cellular data

transmission to send test results to a cloud server, Telemed-Gluconet.

SOLUSmobile Blood Glucose Test Strips

The SOLUSmobile Blood Glucose Test Strips are to be used with the SOLUSmobile Blood Glucose Meter to quantitatively measure glucose in fresh capillary whole blood from the finger and the forearm. These test strips are intended for use by a single patient with diabetes mellitus at home and should not be shared..

SOLUSmobile Control Solutions

The SOLUSmobile Control Solutions are for use with SOLUSMobile Meter and Test Strips to check that the meters and test strips are working together properly and that the test is performing correction. A control test that falls within the stated range indicates the user technique is appropriate and the test strip and meter are functioning properly.

6. Comparison to Predicate Device

For the proposed SOLUSmobile device, the modifications from the cleared SOLO V2 (K093764) include the following:

- **Replacement of the original feature of cabled data download to a PC by automatic wireless data transmission capable of sending the test results over the wireless cellular network to a Central Data Repository at a preset time interval in a day**

This feature allows the meter to use cellular data transmission to automatically send test results to a Central Data Repository (Cloud Server) at a preset time interval in a day.

- **Addition of an Airplane Mode Button**

This feature allows users to turn on or off the meter's wireless communications capabilities. When the button is in the "Off" position, communications capabilities are available. When the button is in the "On" position, the communications module is turned off.

- **Change of the meter's battery from Alkaline AAA battery to a rechargeable Li-polymer battery**

This feature allows users to recharge the meter's Li-polymer battery by plugging the Micro USB connector on the charging cable into the Micro USB port on the right hand side of the meter and connecting the other end of the charging cable to an electrical outlet.

- **Addition of backlight**

This feature allows users to see the LCD display more clearly when the meter is on. The backlight will be automatically on when the meter is on and the backlight will be automatically off when the meter is off.

- **Addition of an ear phone jack**

This feature allows users to hear the meter's audible output through an ear phone plugged into the meter's ear phone jack.

- **Rearrangement of control buttons**

The location of Up(**Y**▲)/Down(▼**N**) Buttons, Language Selection Button(), the "**M**" Left Function Button and "**R**" Left Function Button are rearranged and placed at the front side of the meter, right below the LCD screen and speaker slot.

- **Modification of outer plastic case dimension**

The plastic cover of the meter is modified to be longer (19mm), slightly wider(3.3mm) and thicker (2.8 mm) in dimension than that of the predicate SOLO V2 (Model 6131). No changes were made to the materials used for. The change was made for style purposes and accommodating the addition of an embedded cellular communications module within the meter.

Product sterilization, shelf-life, and biocompatibility are unaffected by the modifications and are equivalent to the legally marketed the SOLO V2 device (K093764).

These modifications are eligible for the Special 510(k) process, as they do not

affect the intended use or alter the fundamental scientific technology of the cleared device.

7. Performance Studies

The device (SOLUSmobile) is intended for single-patient use. Cleaning and disinfection of the devices are different processes. Cleaning is the process of removing dirt or touch contaminants while disinfection is the process of killing viruses.

Disinfection studies were performed on the meter and lancing device by an outside testing service to determine the disinfection efficacy of the meter and lancing device to the recommended cleaning and disinfection procedure, and its effectiveness in preventing the spread of blood-borne pathogens, particularly hepatitis B virus (HBV). Clorox® Bleach Germicidal Wipes (EPA Reg. No. 67619-12) was validated, demonstrating complete inactivation of live virus for use with the meter and lancing device. The robustness studies were also conducted and demonstrated that there was no change in performance or in the external materials of the meter and lancing device after 11,000 cycles of cleaning and 11,000 cycles of disinfection to simulate the claimed 3 years of use by lay users.

A risk assessment following the standard ISO 14971:2007[1] was performed and verification and validation testing was conducted to assess the changes to demonstrate that the design outputs of the modified device meet the predetermined acceptance criteria of the design input requirements. All hazards caused by the changes to the predicate device and the cleaning and disinfection were within the acceptable range after risk mitigation. Therefore, the SOLUSmobile is substantially equivalent to the predicate the SOLO V2 (K093764).

8. Conclusion

The SOLUSmobile Blood Glucose Management System, Model 6134 demonstrates satisfactory performance, is suitable for its intended use, and is substantially equivalent to the predicate device.

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[1] ISO 14971:2007. *Medical devices - Application of risk management to medical devices.*

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 28, 2013

Biotest Medical Corporation
C/O Fred Lee
No. 3-2, Chien-kuo Road
TEPZ Tantzu, 427, TAICHUNG
TAIWAN

Re: K123559
Trade/Device Name: SOLUSmobile Blood Glucose Management System, (Model 6134)
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: II
Product Code: NBW, CGA, JJX
Dated: June 21, 2013
Received: June 24, 2013

Dear Mr. Lee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carol C. Benson -S for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K123559

Device Name: SOLUSmobile Blood Glucose Management System, Model 6134

Indications for Use:

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Prescription Use X AND/OR Over-The-Counter Use X
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Devices and Radiologic Health (OIR)

Katherine Serrano -S

Division Sign-Off
Office of In Vitro Devices and Radiologic Health

510(k) k123559